REMARKS / ARGUMENTS

I. Amendments

The reference to related application on page 1 of the specification is updated as required.

Claims 8-11, 26-28, 35, and 39-45 are pending and under examination. Claim 46 is added.

Claim 8 is amended to remove the optional feature to new claim 46. Claims 9 and 40 are amended to depend on new claim 46. Because claim 46 depends on and is drawn directly to subject matter in original claim 8, the Examiner is requested to examiner claim 46.

Claims 26-28 are amended, without prejudice or disclaimer, to replace --Chlamydia-- with *Chlamydia pneumoniae*. The amendment is supported throughout the specification, particularly the examples.

Because these amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested. Applicants retain the right to present claims drawn to the cancelled subject matter in a divisional application(s).

II. Rejection of Claims 26-28 and 43-45 under 35 U.S.C. §112 first paragraph

The Examiner rejects claims 26-28 and 43-45 under 35 U.S.C. §112 first paragraph (enablement). Applicants traverse. Claims 26-28 are amended to replace --Chlamydia-- with *Chlamydia pneumoniae* as required by the Examiner, thereby obviating the rejection.

III. Rejection of Claims 8-11, 35 and 39-42 under 35 U.S.C. § 103(a) – Nat. Genet. 62(3):880-886 (Kalman') and US patent 6,449,294 ('Griffais')

The Examiner's citation of Kalman et al Nat. Genet. April 1999. 62(3):880-886 is not understood. Applicants cannot locate such a reference and assume the

intended citation is Kalman et al. Nature Genetics. April 1999. 21:385-389 (reference A35 on IDS filed January 14, 2004).

The Examiner rejects claims 8-11 and 39-42 under 35 U.S.C. §103(a) as being obvious in view of Kalman in combination with Griffais. Applicants traverse.

(a) What the instant application teaches

The presently amended claims are directed to vaccine vectors comprising a nucleic acid molecule encoding specific proteins (SEQ ID NO: 2, 4 and 6), to pharmaceutical compositions comprising such nucleic acid molecules, and to methods of preventing or treating Chlamydia infection.

As shown in Examples 1-9 in the specification, nucleic acid vaccine vectors of the invention elicited a protective response against *C. pneumoniae* infection in mice. The specification provides complete details of how to make and use nucleic acid vaccines encoding SEQ ID NO: 2, 4 and 6 and demonstrates that such vaccines are indeed useful.

(b) What Griffais teaches

Griffais sequenced fragments of the *C. pneumoniae* genome and identified approximately 1300 putative open reading frames which might encode proteins (see Table 1 of Griffais). As noted by the Examiner, none of the sequences disclosed by Griffais are those recited in the instant claims.

Using computer-implemented sequence homology analysis, Griffais compared these sequences to those found in sequence databases and, where possible, assigned putative functions to the open reading frames, based on their homology to known sequences.

The experimental work conducted by Griffais ends here.

Griffais postulates that any of the 1296 putative ORFs they disclosed might work as a vaccine and then provides a discussion of typical approaches one might use to make a DNA-based vaccine.

(c) What Kalman teaches

Kalman sequenced the entire genome of two *Chlamydia pneumoniae* strains by cloning random fragments into a M13 vector for automated sequencing. Kalman discloses no expression data nor suggests that the sequences be expressed.

(d) There is no motivation to combine Kalman with Griffais

There is no explicit suggestion in Kalman's disclosure to use any of the sequences of the *C. pneumoniae* genome as a DNA-based vaccine. Neither is there an implicit suggestion, since Kalman's sequences are not in expressible form and are incapable of being expressed as is required in a DNA-based vaccine.

Similarly, there is no suggestion in Griffais to use any of Kalman's sequences as DNA-based vaccine, let alone the particular sequence coding for the 76kDa protein. Griffais' disclosure actually leads a skilled person away from using Kalman's sequences because, with the approximately 1300 putative open reading frames postulated by Griffais, a skilled person would already have his hands full trying make the 1300 sequences into vaccines, as directed by Griffais.

(e) There is no reasonable expectation of success in the combination of Kalman and Griffais

A skilled person cannot reasonably expect that combining Kalman with Griffais would lead to a successful DNA vaccine, as is claimed in the instant application. Applicants have determined that identifying a suitable *C. pneumoniae* sequence for use as a vaccine is no easy matter and that actually, only a few of the open reading frames of the *C. pneumoniae* genome can be used as vaccines.

In the attached Declaration under 37 CFR § 1.132 filed in US application 10/334,137, inventor Andrew Murdin discussed that, as part of the assignee's *C. pneumoniae* vaccine programme, 36 *C. pneumoniae* ORFs were tested in the *in vivo* mouse model described in the Examples. Only 8 of the 36 ORFs (i.e. 22%) provided a protective effect.

Kalman's contribution is the sequence of the *C. pneumoniae* genome containing thousands of ORFs. Griffais offers a generic description of standard vaccine methodology. Even if a skilled person is motivated to combine these teachings, to search effectively by trial and error for the vaccine instantly claimed is, in essence, searching for the proverbial needle in a haystack. Based on Griffais and Kalman, the skilled person could not practice the instantly claimed invention without undue experimentation. Griffais and Kalman therefore does not render obvious the instantly claimed subject matter. The insufficiency of their combined teachings is made clear by Applicants' own work showing that relatively few ORFs of *C. pneumoniae* are useful in the preparation of vaccines.

Withdrawal of the rejection under 35 U.S.C. § 103(a) in view of Griffais and Kalman is requested.

IV. Concluding Remarks

In view of the above amendments and remarks, reconsideration and favorable action on all pending claims are respectfully requested. If any questions or issues remain, the Examiner is invited to contact the undersigned at the telephone number set forth below so that a prompt disposition of this application can be achieved.

If a fee is required for an extension of time which is not accounted for, such an extension is requested and the U.S.P.T.O. is authorized to withdraw from our Deposit Account Number 19-0741 any fee required.

Respectfully submitted,

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